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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,297	10/17/2001	Oron Yacoby-Zeevi	01/22716	5033

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,297	YACOBY-ZEEVI, ORON	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,11-17 and 19-50* is/are pending in the application.

4a) Of the above claim(s) *38-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,11-17 and 19-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/2004 has been entered.

Applicants amendment of the specification and claims 1-5, 11-17, and 19-37 in the paper of 5/19/2004 is acknowledged. Claims 1-5, 7-9, 11-17 and 19-50 are present for examination. Applicants' arguments filed on 5/19/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 38-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-9, 11-17 and 19-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (2-5 dependent on), 7(8,9 11-12 dependent on), 13 (14-17, 19-20 dependent on), 21 (22-25 dependent on), 26 (28-30 dependent on) and 31 (32-37 dependent on) are indefinite in that it is confusing in the recitation of the two words "implantation" and "implanting" in each claim. Specifically the use of both forms of 'implant" in the claim make the claims confusing because it is believed that it is applicants intent to give each of "implantation" and "implanting" different meanings in the referred to claims. For instance, in the use of the word "implantation" such as a method of improving embryo implantation, it is believed that it is applicants intent that they are referring to a method of improving the actual act of "embryo implantation" which is refers to the actual attachment of the embryo to the uterus wall, whereas in the use of the word "implanting" such as implanting the embryo in a receptive uterus, it is believed that applicants are referring to the act of "inserting" or "placement of" the embryo into the uterus and not the physiological/developmental act of "implantation". Clarification and potentially amendment by applicants is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 11-17 and 19-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 7-9, 11-17 and 19-37 are rejected under this statute because applicants newly amended recitation to "purified recombinant heparanase having at least 95% homology to SEQ ID NO: 1" is not supported by the original specification, thus this referred to subgenus is considered new matter. Specifically applicants recitation of the subgenus having 95% homology is not supported by the original specification. Applicants arguments regarding support for such a limitation is acknowledged, however found non-persuasive.

Claims 1-5, 7-9, 11-17 and 19-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of improving embryo implantation, the method comprising contacting an embryo with an effective amount of purified recombinant heparanase having at least 95% homology to SEQ ID NO: 1 and inserting the embryo in a receptive uterus, wherein said embryo and uterus are from the same species, does not reasonably provide enablement for any method of improving embryo implantation, the method comprising contacting any embryo with an effective amount of purified recombinant heparanase having at least 95% homology to SEQ ID NO: 1 and inserting the embryo in any receptive uterus. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-5 are so broad as to encompass any method of improving embryo implantation, the method comprising contacting any embryo with an effective amount of purified recombinant heparanase having at least 95% homology to SEQ ID NO: 1 and inserting the embryo in any receptive uterus, wherein said embryo and uterus may be from different species. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of species broadly encompassed by the claims, including methods involving any embryos and uterus from any species including those methods in which the embryo and uterus are not from the same species. Since the claimed methods read on any species of embryo and uterus, including methods of cross-species implantation and applicants have merely shown the success of the disclosed method wherein both the embryo and

uterus are from murine species, those embodiments wherein said embryo and uterus are from different species are not enabled.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those species in which the disclosed methods are successful is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

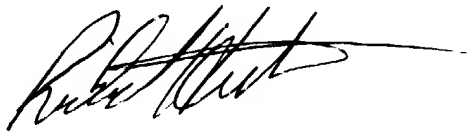
Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
1/9/2003